UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/872,705	06/01/2001	William J. Roberts	1400-002	2502

33461 7590 04/29/2005

SULLIVAN LAW GROUP
1850 NORTH CENTRAL AVENUE
SUITE 1140
PHOENIX, AZ 85004

EXAMINER	
QAZI, SABIHA NAIM	
ART UNIT	**PAPER NUMBER**
1616	

DATE MAILED: 04/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/872,705	ROBERTS, WILLIAM J.	
	Examiner	Art Unit	
	Sabiha Qazi	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 December 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15 and 22-61* is/are pending in the application.

4a) Of the above claim(s) *3-7,11-13,15,29-33,38-40 and 42-48* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,8-10,14,22-28,34-37,41 and 49-61* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *3-7,11-13,15,29-33,38-40 and 42-48* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

RD

Non-Final Office Action

Claims 1-61 are pending. Claims 1, 2, 8-10, 14, 22-28, 34-37, 41 and 49-61 are examined. Claims 16-21 have been canceled and claims 3-7, 11-13, 15, 29-33, 38-40, and 42-48 have been withdrawn. No claim is allowed at this time.

Examiner respectfully request the Applicant to re-draft the claim by drawing the structure of the claimed compounds, so that the invention could be clear and this will be good for all the parties including public. Examiner notes that claim 1 is a composition claim and not the method of use.

Examiner also notes, that methoxymethyl ether at 17-position of testosterone may be new but Applicant is not claiming compounds, claims are drawn to composition and method of use.

Status of Application

Double Patenting rejection is withdrawn, as arguments are found persuasive. However, 112 (2) is maintained (in part) as claims 16-21 are cancelled. Other rejection is maintained for the same reasons as set forth in our previous office action because claims are not amended.

Rejection of promoiety is maintained for the same reason as set forth in our previous office action. Applicants need to explain methoxymethyl ether in the rejected claims. Rejection will be withdrawn when the arguments would be found persuasive.

Presently claimed invention is drawn to a compound for supplementing the concentration of parent androgen as in claim 1.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 1, 2, 8-10, 14, 22-28, 34-37 41 and 49-61 are rejected under 35 U.S.C. 112, second paragraph, is maintained (in-part).

3. What is intended by a "promoiety comprising".

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> *The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.*

Claims 1, 2, 8-10, 14, 22-28, 34-37, 41 and 49-61 rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the composition of testosterone methoxymethyl ether, (17β-methoxymethylandrost-4-ene-3-one compound, [0023] on page 9 of the specification) does not reasonably provide enablement for the compositions of alkoxymetthyl ether of any androgen as has been claimed. The specification also does not disclose the methods for increasing concentration of a "parent androgen" (claim 26) and "converting the parent composition in *vivo* within human being" (claim 27). There is no mention how this complex is formed and the advantages of it. Similarly claiming the composition and methods for "androgen" is broad see details below. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the

invention commensurate in scope with these claims.

MPEP 2164.01(c) states:

> When a compound or composition claim is limited by a particular use, enablement of that claim should be evaluated based on that use.

Factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in In re Colianni, 195 USPQ 150, 153 (CCPA 1977), have been clarified by the Board of Patent Appeals and Interferences in Ex parte Forman, 230 USPQ 546 (BPAI 1986), and are summarized in In re Wands (858 F2d 731, 737, 8 USPQ2d 1400, 1404 (Fed Cir. 1988). Among these factors are: (1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

When the above factors are weighed, it is the examiner's position that one skilled in the art could not practice the invention without undue experimentation.

(1) The nature of the invention: The claims are drawn to a composition for supplementing the concentration of a parent androgen in a subject in vivo, the parent androgen having a skeletal structure including a 17 position and the parent androgen further having a 17 β-hydroxy group comprising a 17- β-hydroxy hydrogen appended to the 17 position.

(2) The predictability or unpredictability of the art: " . In other words, for the claim to be enabled, the specification must teach how to make the claimed composition without undue experimentation and must teach how to use the composition for at least one pharmaceutical use without undue experimentation. There is lack of predictability in the in the pharmaceutical art. The amount of guidance or direction needed to enable the invention is inversely related to the amount of knowledge in the state of the art as well as the predictability in the art. *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970). The "amount of guidance or direction" refers to that information in the application, as originally filed, that teaches exactly how to make or use the invention. The more that is known in the prior art about the nature of the invention, how to make, and how to use the invention, and the more predictable the art is, the less information needs to be explicitly stated in the specification. In contrast, if little is known in the prior art about the nature of the invention and the art is unpredictable, the specification would need more detail as to how to make and use the invention in order to be enabling. >See, e.g., *Chiron Corp. v. Genentech Inc.*, 363 F.3d 1247, 1254, 70 USPQ2d 1321, 1326 (Fed. Cir. 2004) ("Nascent technology, however, must be enabled with a 'specific and useful teaching.' The law requires an enabling disclosure for nascent technology because a person of ordinary skill in the art has little or no knowledge independent from the patentee's instruction. Thus, the public's end of the bargain struck by the patent system is a full enabling disclosure of the claimed technology."

[I]n the field of chemistry generally, there may be times when the well-known unpredictability of chemical reactions will alone be enough to create a reasonable doubt as to the accuracy of a particular broad statement put forward as enabling support for a claim. This will especially be the case where the statement is, on its face, contrary to generally accepted scientific principles. Most often, additional factors, such as the teachings in pertinent references, will be available to substantiate any doubts that the asserted scope of objective enablement is in fact commensurate with the scope of protection sought and to support any demands based thereon for proof.

The scope of the required enablement varies inversely with the degree of predictability involved, but even in unpredictable arts, a disclosure of every operable species is not required. A single embodiment may provide broad enablement in cases involving predictable factors, such as mechanical or electrical elements. *In re Vickers*, 141 F.2d 522, 526-27, 61 USPQ 122, 127 (CCPA 1944); *In re Cook*, 439 F.2d 730, 734, 169 USPQ 298, 301 (CCPA 1971). However, in applications directed to inventions in arts where the results are unpredictable, the disclosure of a single species usually does not provide an adequate basis to support generic claims. *In re Soll*, 97 F.2d 623, 624, 38 USPQ 189, 191 (CCPA 1938). In cases involving unpredictable factors, such as most chemical reactions and physiological activity, more may be required. *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970) (contrasting mechanical and electrical elements with chemical reactions and physiological activity). See also *In re Wright*, 999 F.2d 1557, 1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993); *In re Vaeck*, 947 F.2d 488, 496, 20 USPQ2d 1438, 1445 (Fed. Cir. 1991). This is because it is not obvious from the disclosure of one species, what other species will work. See MPEP 2164.03.

(4) The amount of direction or guidance presented: There is ***no*** guidance in the disclosure on how to make and/or use the invention. The specification lacks any direction and/or guidance on how to make and/or use the invention.

Claiming the composition and methods for "androgen" is broad.

See In re Dreshfield, 110 F.2d 235, 45 USPQ 36 (CCPA 1940), gives this general rule: "It is well settled that in cases involving chemicals and chemical compounds, which differ radically in their properties it must appear in an applicant's specification either by the enumeration of a sufficient number of the members of a group or by other appropriate language, that the chemicals or chemical combinations included in the claims are capable of accomplishing the desired result."

The courts have further interpreted undue experimentation as requiring "ingenuity beyond that to be expected of one of ordinary skill in the art" (Fields v. Conover, 170 USPQ 276 (CCPA 1971)) or requiring an extended period of experimentation in the absence of sufficient direction or guidance (In re Colianni, 195 USPQ 150 (CCPA 1977)). Additionally, the courts have determined that "... where a statement is, on its face, contrary to generally accepted scientific principles", a rejection for failure to teach how to make and/or use is proper (In re Marzocchi, 169 USPQ 367 (CCPA 1971).

(5) The presence or absence of working examples: There are no working examples and/or data *in vivo* or *vitro* to support the claimed invention. The disclosure does not contain any

working examples.

Furthermore, laim 54-56 is drawn to complexing the composition with an hydroxyl beta cyclodextrin. There is no mention how this complex is formed and the advantages of it. Similarly claiming the composition and methods for "androgen" is broad

A disclosure should contain representative examples, which provide reasonable assurance to one skilled in the art that the compounds fall within the scope of a claim will possess the alleged activity. See In re Riat et al. (CCPA 1964) 327 F2d 685, 140 USPQ 471; In re Barr et al. (CCPA 1971) 444 F 2d 349, 151 USPQ 724.

(6) The quantity of experimentation necessary: Since there are no working examples, no data, and no direction and/or guidance presented in the disclosure, one skilled in the art at the time of invention would have to go through undue experimentation to make and/or use the presently claimed invention.

For rejection of composition claims MPEP 2164.01(c) states:

> When a compound or composition claim is limited by a particular use, enablement of that claim should be evaluated based on that use.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> *A person shall be entitled to a patent unless –*
>
> *(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.*

1. Claims 1, 2, 8-10, 14, 22-28, 34-37, 41 and 49-61 are rejected under 35 U.S.C. 102(e) as being anticipated by Cowan et al. (Clinical Chemistry 43:7, pp 1261-70, (1997)). The reference discloses that testosterone esters such as testosterone propionate and testosterone ensnthate increase the testosterone levels when given to an individual playing sports. See Pages 1270 and 1271.

Testosterone esters are prodrug of the compounds which when administered converts the prodrug into testosterone and thus increases the level of testosterone in the body. Presently invention as claimed is drawn to a prodrug of testosterone and other androgens where instead of esters methoxymethyl ether of testosterone/androgen are claimed. Even if the methoxymethyl ethers are not mentioned, the function to increase the level of androgen/testosterone has been taught, the instant invention is inherently taught by the prior art.

Examiner notes, that the applicants have showed no criticality or specific difference in the activity or action of the invention. The cleavage at 17-position to form OH and mechanism is considered inherent. The prodrug as claimed is expected to give the same compound and same activity i.e. increase in androgen/ testosterone levels.

See Exparte Novitski, 26 USPQ 2d 1389 (January 22, 1993) which is decision of USPTO Board of Appeals, holding to be inherent and not patentable, inoculating healthy plants with a known plant inoculant's, employed in the prior art to protect them against phytopathogenic fungi. Novitski discovered that the known plant inoculants would also protect them against root dwelling plant pathogenic nematodes, a discovery neither known nor appreciated by the prior art.

The step of inoculating plants with the same inoculants necessarily and inherently protects them against nematodes.

See Atlas Powder versus Ireco, 51 USPQ 2d 1943, (Fed. Cir. 1999), holds the failure of those skilled in the art to contemporaneously recognize an inherent property, function, or ingredient of a prior art reference does not preclude a finding of anticipation. Whether or not an element is inherent in the prior art is a fact question. Inherency is not necessarily conterminous with knowledge of those of ordinary skill in the art, who may not recognize the inherent characteristics or functioning of the prior art. However the discovery of a previously unappreciated property of a prior art composition does not render the old composition new to the discoverer.

The fact that prior art taught away from the claim is, in fact, only a showing that prior art did not recognize the inherent function. This lack of contemporary understanding did not defeat the showing of inherency.

As is clear from the above discussion and citations that the instant invention is a known process of cleaving the ester and ether would have been the same and would increase the level of androgens, the specific androgen obtained would surely depend on the parent androgen, therefore is inherently taught by the prior art of record.

2. Claims 1, 2, 8-10, 14, 22-28, 34-37, 41 and 49-61 are rejected under 35 U.S.C. 102(e) as being anticipated by Arnold (US Patent 5,880,117). The reference discloses a method of inceasing testosterone levels in humans by administering the precursor 4-androstene diol. The compound used in prior art contains 3-one; however, in human body the said precursor is converted to testosterone see claims 1-4 of the reference.

Therefore, the method of increasing the testosterone level is inherently taught. The detailed reasons and case laws are cited above.

3. Claims 1, 2, 8-10, 14, 22-28, 34-37, 41 and 49-61 are rejected under 35 U.S.C. 102(e) as being anticipated by Earnest et al. (Eur. J. Appl. Physiol. (2000) 81 :229-232). The reference discloses the transformation of androgenic hormone precursors for testosterone in an androgenic pathway to testosterone. Various male subjects study and the results are disclosed. The precursors as presently claimed is expected to give testosterone as has been disclosed by the prior art. See the entire document especially abstract, , methods and results on page 230, Table 1 on page 231and discussion on pages 231 and 232.

Therefore, the method of increasing the testosterone level is inherently taught. The detailed reasons and case laws are cited above

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sabiha Qazi whose telephone number is (571) 272-0622. The examiner can normally be reached on any business day.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (571) 272-0887. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SABIHA QAZI, PH.D
PRIMARY EXAMINER

Friday, April 8, 2005